



June 4, 2014

The Honorable Kathleen Sebelius
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW, Room 120F
Washington, DC 20201

Dear Secretary Sebelius:

On April 25th the Food and Drug Administration (FDA) released a long overdue proposed rule, which we will be formally commenting on, to begin regulating electronic cigarettes, cigars and other tobacco products under the Family Smoking Prevention and Tobacco Control Act. Until FDA issues a final rule deeming these tobacco products subject to its regulatory authority, these tobacco products will remain entirely free of regulation, with significant adverse consequences for public health. The three years it took to develop the proposed rule was too long.

Therefore, we urge you to adopt a final rule no later than 12 months from the publication of the proposed regulation.

The public health consequences of the delay in issuing the proposed deeming rule have been significant. While FDA, HHS and OMB were deliberating, use of e-cigarettes proliferated. In the current unregulated marketplace the Centers for Disease Control and Prevention found that the percentage of high school students who have ever tried e-cigarettes doubled from 4.7 percent to 10 percent from 2010 to 2011. Reports of poisonings from accidental ingestion of the nicotine-containing liquid used to refill e-cigarettes have increased dramatically. Consumption of another unregulated product, cigars, has more than doubled since 2000. The cigar marketplace increasingly consists of cheap, flavored cigars that appeal to youth. Each day, more than 2,700 kids under 18 years old try cigar smoking for the first time, a figure that now approaches the 3,200 kids who try cigarettes for the first time every day.

Manufacturers of the deemed products will no doubt argue that the issues before the FDA are so complex as to require endless study. Such tactics are a familiar and inevitable response from those who profit from the unregulated sale of these products

and who continue to market these products to kids. Consumers need these common sense public health protections now.

In addition, there are matters vital to the protection of the public health that are not addressed in the proposed rule. Prominent among them is the prohibition of characterizing flavors and marketing that appeal to young people. It is essential that the FDA begin the investigation of these issues immediately and either address these matters in the final “deeming” rule or, at the very least, issue a proposed rule to address each of these issues within twelve months of the publication of the proposed deeming rule. At worst, FDA should be in a position to publish a final rule on these issues shortly after the deeming rule becomes final.

Further, the agency’s proposed rule does nothing to address the widespread availability of candy-flavored, nicotine-laced liquid used in e-cigarettes and related products in containers that are not child-proof. CDC reported earlier this year that the number of e-cigarette exposure calls per month to poison centers rose from one per month in September 2010 to 215 per month in February 2014. More than half of these calls to poison hotlines were to report incidents involving children aged five and under. Given the urgency of this threat to our nation’s children, FDA should issue a proposed rule to require child-resistant packaging of e-liquids and related products within 90 days of the date of this letter so a final rule can be issued at the same time as the final deeming rule.

In conclusion, given the importance of making this rule final as soon as possible and addressing the important issues for which no proposal was made, it is critical that the Administration and the FDA:

1. Issue a final deeming rule within twelve months of the date FDA published its proposed rule.
2. Incorporate provisions governing flavors and marketing in the final deeming rule OR issue proposed rules to prohibit characterizing flavors and impose additional marketing restrictions within twelve months of the date of publication of the proposed deeming rule and finalize those rules shortly after the deeming rule becomes final.
3. Issue a proposed rule to require child-resistant packaging of e-liquids and related products within 90 days of the date of this letter and issue a final rule at the same time as the final deeming rule.

Given the resources at FDA’s disposal, there is no reason why this process should not be completed within this time. Lives are at stake. Business as usual will not get the job done.

Sincerely,



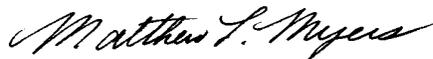
Christopher W. Hansen
President
American Cancer Society Cancer Action Network



Nancy A. Brown
Chief Executive Officer
American Heart Association



Harold Wimmer
National President and CEO
American Lung Association



Matthew L. Myers
President
Campaign for Tobacco Free Kids



Robin Koval
President and CEO
Legacy

cc: Margaret Hamburg, MD, Commissioner, Food and Drug Administration
Mitchell Zeller, JD, Director, Center for Tobacco Products